IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* ELLSWORTH ASSOCIATES, LLP, Plaintiff-Relator, v. CVS HEALTH CORPORATION, *et al.*, Defendants.	Case No.: 2:19-cv-2553-JMY

REPLY IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

The opening brief flattened the relator's theory of this False Claims Act (FCA) case to the point that the opposition brief had to reimagine the case at every turn to find colorable arguments why it should not be dismissed. But the opposition fails in its task of trying to reinvent its allegations to find some actionable fraud on the government. There is no fraud here, and defendants should not be made to defend against these unsustainable claims any longer.

Strikingly, the relator *admits* that it is not challenging "SilverScript's preference for brand-name drugs on its formulary [nor] contend[ing] that SilverScript's exclusion of generic drugs from its formulary, standing alone, is fraudulent." Opp. 1. It has pulled the rug out from under its own case. If the brand preference is not fraudulent, how can there be a fraud on the government?

The relator's reimagined theory is that any alleged violation of an antitrust law or consumer-protection statute or misleading communication states a claim for fraud on the government. But the FCA is not a consumer-protection statute nor concerned with general legal compliance. The relator's effort to recast this FCA case into an antitrust case is untenable, and it underscores that this case never had legal merit to begin with. The relator's attempt to conjure up some way in which defendants engaged in fraud by participating in the ordinary workings of the Part D program comes up short. It has not plausibly nor particularly alleged that any defendant defrauded the Part D program, and no amount of retooling during motions practice can fix that core problem with the second amended complaint (SAC). This case should be dismissed.

ADDITIONAL BACKGROUND

Some additional background information is necessary because the relator's brief labors under two basic misperceptions about the FCA and Part D formulary exceptions.

First, the FCA "protect[s] government funds and property from fraudulent claims" (*United States ex rel. Ryan v. Endo Pharm. Inc.*, 27 F. Supp. 3d 615, 621 (E.D. Pa. 2014)) and "penalizes only false claims" (*United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 177 (3d Cir. 2019)).

It is "not designed to reach every kind of fraud practiced on the Government" (*United States v. McNinch*, 356 U.S. 595, 599 (1958)), "not 'an all-purpose antifraud statute,' or … for punishing garden-variety breaches of contract or regulatory violations" (*Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) (citation omitted)), and "not a blunt instrument to enforce compliance with all … regulations" (*United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (citation omitted)). That "allegations may invoke other grounds for criminal or civil liability" does not mean they "sound in the FCA." *United States ex rel. Travis v. Gilead Scis., Inc.*, 2022 WL 991382, at *8 (E.D. Pa. Apr. 1, 2022). The relator's contention—that we "confused CMS's limited role in Part D oversight with … overarching obligations to comply with federal law" (Opp. 21)—shows only that the *relator* is confused.

Second, exceptions to a Part D plan's CMS-approved formulary are *not* available to reduce costs; a formulary exception is only available when using an on-formulary drug would be less *clinically* effective. A plan sponsor must grant a formulary exception when "it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement … , and that the drug would be covered but for the fact that it is an off-formulary drug." 42 C.F.R. § 423.578(b). That is, a prescriber must determine that the off-formulary drug is "medically necessary to treat the enrollee's disease or medical condition because … [a]ll of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both." 42 C.F.R. § 423.578(b)(5)(i); 42 U.S.C. § 1395w-104(h)(2); CMS, *Part C and D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance* § 40.5.3 (Aug, 3, 2022), perma.cc/TWV4-NGN4. A prescriber's accounting for adverse effects or comparative effectiveness of drugs on and off formulary is a *clinical* determination, not about cost.

That is why CMS has repeatedly conveyed that formulary exceptions are medically

necessary only when the on-formulary drug would have adverse *clinical* effects.[1] And the U.S. Department of Health and Human Services (HHS) Medicare Appeals Council—which reviews enrollee appeals from denials of formulary exceptions—expressly holds that "[t]he formulary exception process [] may not be used solely on the basis that a drug is cost prohibitive to an enrollee." *In the Case of A.S. Cmty. CCRx Claim for Prescription Drug Benefits (Part D)*, 2013 WL 7872029 (HHS Medicare Appeals Council Apr. 15, 2013). The relator's repeated suggestion that formulary exceptions must be routinely provided based on cost comparisons is wrong.

With these two preliminary matters addressed, we turn to the substance of the opposition.

ARGUMENT

I. THE COURT SHOULD DISMISS BECAUSE COMPLYING WITH PART D RULES IS NOT FRAUD.

The relator's claims should be dismissed because, as relator now concedes, including a brand drug but not its generic equivalent on a formulary is fully compliant with Part D rules and in no way fraudulent. For all its bluster, the relator now disclaims the SAC's central theory and instead insists that antitrust violations underlie its FCA claims. But antitrust violations alone do not violate the FCA, nor can the relator come close to properly alleging an antitrust case.

A. The relator concedes that preferring a brand over a generic drug on a formulary complies with Part D rules.

As explained in the opening brief (at 15-21), there is nothing "false" about dispensing brand drugs consistent with a Part D formulary decision to favor brand drugs over their generic equivalents. The relator now confesses that "there may be circumstances in which legitimate market forces would justify" plan sponsors covering brand drugs but not their generic equivalents

[1] *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4194, 4352 (Jan. 28, 2005) ("tiering exceptions may be connected to demonstrated adverse effects based on previous use of the lower tiered drug" or "exceptions may be linked to predictive adverse effects based on knowledge of the enrollee's medical condition."); *id.* at 4355 ("We agree that where an enrollee's prior use of a drug has proven ineffective or caused adverse consequences to the enrollee's health, the plan must not require the use of the formulary drug as a condition in the exceptions process.").

because it could "lead to lower prices for consumers." Opp. 19. Not only does this explain why CMS has repeatedly allowed this practice, it also admits what defendants said all along—that such arrangements enable SilverScript to secure a lower net cost for drugs. That is not fraud.

B. The relator's effort to recast this FCA case as an antitrust case fails.

Having torpedoed its central theory by conceding that dispensing brand drugs consistent with an approved Part D formulary does not violate the FCA, the relator now argues that those same allegations constitute an illegal agreement under Section 1 of the Sherman Act and violate the FCA for that reason. Opp. 15-21. But no one certified compliance with antitrust laws when submitting Part D claims, and the relator fundamentally misunderstands Section 1 in any event.

1. To start, an antitrust violation cannot serve as the predicate for an FCA claim unless the relator establishes that the defendants expressly or impliedly certified compliance with the antitrust laws when submitting claims for payment and that compliance with the antitrust laws was "material" to the government's payment decision. *Escobar*, 579 U.S. at 190.

But defendants did *not* certify compliance with the antitrust laws when submitting claims to Part D, and the relator does not point to any such certification. As a result, defendants cannot possibly have "falsely" made such a certification. Additionally, the relator has not alleged any facts on which to conclude that compliance with the antitrust laws was "material." *Escobar*, 579 U.S. at 190. The relator does not allege *any* information from which to conclude that CMS routinely refuses to pay claims because of alleged antitrust violations. Indeed, that the government has known about these allegations for years and taken no action is strong proof of immateriality.

The cases the relator cites only prove our point. The relator's lead authority is a *settlement*, which is not support for any legal proposition at all. Even so, there, a drug manufacturer reached a global settlement after a multi-agency investigation of *both* FCA *and* antitrust violations. Press Release, U.S. Dep't of Justice, *Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History* (July

11, 2019), perma.cc/6KJZ-8CRK (civil settlement "resolve[d] claims that the marketing of Suboxone caused false claims to be submitted," while a "separate agreement with the [FTC] … resolve[d] claims that it engaged in unfair methods of competition").[2] These settlements prove what we have said: that the FCA does not punish antitrust violations; the antitrust laws do.

The relator's sole case is even further afield. In *United States v. Beatrice Foods Co.*, the government alleged that the defendants conspired to fix prices and then submitted "collusive and rigged bids" to federal agencies. 330 F. Supp. 577, 579 (D. Utah 1971). The court agreed that FCA and Sherman Act liabilities are not mutually exclusive—allowing the government to recover under both if "the elements of liability [under the FCA] are established" even if those acts "also constitute, because of other elements, violation of the Sherman Act." *Id.* at 582. But the relator does not contend there was bid-rigging between competitors vying to serve the Part D program. No, the relator argues that *because* it alleges conduct that allegedly violates the Sherman Act, that same conduct necessarily violates the FCA. That is an unsupportable proposition.

2. Even if an antitrust violation could serve as a predicate for an FCA violation (and it cannot here), the relator fails drastically in its attempt to allege a Sherman Act Section 1 violation. Indeed, the relator ignores the elements of a Section 1 claim entirely.

Section 1 prohibits agreements in restraint of trade or commerce. 15 U.S.C. § 1. To plead a Section 1 violation, the plaintiff must allege four elements: "(1) concerted action by the defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action." *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005). As these elements make clear, not all agreements that theoretically restrain trade violate Section 1. Section

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[2] *See also* Press Release, U.S. Dep't of Justice, *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs* (Oct. 1, 2021), perma.cc/DPD4-P28N (alleging violations of the Anti-Kickback Statute, an FCA predicate).

1 only prohibits agreements that are "unreasonably restrictive of competitive conditions." *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993).

Most agreements—including exclusive dealing agreements, which relator tries to allege between Caremark and drug manufacturers—are analyzed under the "rule of reason." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 268 (3d Cir. 2012). Because exclusive dealing agreements "generally pose little threat to competition" and are often procompetitive, "an exclusive dealing arrangement will be unlawful only if its 'probable effect' is to substantially lessen competition in the relevant market." *Id*. at 268-269. To show such a probable effect, plaintiffs must generally show significant market power by the defendant, contracts sufficiently lengthy to prevent meaningful competition, an analysis of anticompetitive effects in view of procompetitive benefits, evidence of coercive behavior, and whether competitors also practice exclusive dealing. *Id*. at 271.

The relator's attempt at alleging an exclusive dealing arrangement in violation of Section 1 falls far short. To start, the relator does not allege the relevant market in which competition is impaired. *North Penn Towns, LP v. Concert Golf Partners, LLC*, 554 F. Supp. 3d 665, 698 (E.D. Pa. 2021) (courts may dismiss complaints that fail to properly allege relevant market); *Fresh Made, Inc. v. Lifeway Foods, Inc.*, 2002 WL 31246922, at *5 (E.D. Pa. Aug. 9, 2022) (dismissing complaint after finding that plaintiff failed to allege a relevant market). Nor does the relator address market power nor compare defendants' market share to that of their competitors.

Putting aside these basic failures, the relator also does not explain how the rebate agreements substantially foreclose competition nor how their alleged anticompetitive effects outweigh their procompetitive benefits. In failing to do so, the relator fails to establish that an antitrust injury was suffered. *Phila. Taxi Assoc., Inc. v. Uber Tech. Inc.*, 886 F.3d 332, 344-345 (3d Cir. 2018) (an antitrust injury requires anticompetitive effect, not financial hardship or otherwise illegal conduct). Indeed, courts have found other prescription drug agreements conditioning rebates on exclusive dealing as *promoting competition*, instead of violating antitrust

laws. *In re Epipen Mktg., Sales Practice and Antitrust Litig.*, 545 F. Supp. 3d 922, 1006-1008 (D. Kan. 2021). What is more, 36 states and D.C. have Medicaid formularies that prefer certain brand drugs over their generic equivalents. That government healthcare programs actively seek these arrangements underscores that they must not view them as harming competition. MTD 7-8.

The SAC nowhere near alleges an antitrust claim and falls even shorter of alleging an FCA claim. The attempt to refashion this FCA case into an antitrust case after conceding there is nothing fraudulent about preferring brand drugs over generics rings hollow and warrants dismissal.

II. THE RELATOR FAILS TO REHABILITATE ANY OF ITS SCATTERSHOT CERTIFICATION THEORIES.

A. State generic substitution laws do not give rise to a false claim.

As our opening brief explained (at 21-32), the relator fails to allege the falsity, materiality, or knowledge necessary to state an FCA claim based on alleged noncompliance with state generic-substitution laws. The relator's opposition fails to demonstrate the SAC met any of these elements.

1. There is no "falsity" under state generic-substitution laws. Though agreeing that generic-substitution laws apply only when a generic equivalent costs less than the brand (Opp. 24-27; SAC ¶ 207), the relator argues that is "complicated and fact-dependent" (Opp. 27) and that it should therefore be allowed to embark on a multi-state fishing expedition to ferret out fraud. That is not how Rule 9(b) works. The relator's *pleading* must identify the fraud, and it has not.

The relator's response on comparative costs is premised entirely on its assertion that SilverScript must grant formulary exceptions and apply Tier 4 cost-sharing to generic equivalents based on cost concerns. Opp. 24-26 & n.17. But that assertion is wrong. *Supra* at 2-3. Without it, the relator's opposition crumbles; the relator has failed to allege that it would have cost the enrollee less to pay cash for a non-covered generic equivalent than to use her Part D coverage to get the brand drug. The relator argues that it "provid[ed] numerous specific examples of actual SilverScript patient claims demonstrating that the generic would have been much cheaper than the brand-name drug." Opp. 26 (citing SAC ¶¶ 394-396, 491, 561-563). But the examples are nothing

of the sort—"[d]enying the option of a formulary exception made her medication more expensive to both this senior and Medicare" (SAC ¶ 396); describing plan and beneficiary costs after the enrollee was given a one-month "tiering exception" (*id.* ¶¶ 487-491); "a flaw in the claims logic" allowed a one-time covered fill of a generic equivalent *(id*. ¶¶ 561-564).

Not one of these "demonstrate[es] that the generic would have been much cheaper" for a patient at the counter because these were all one-off, single-month exception decisions entirely within SilverScript's discretion. To establish noncompliance with a generic-substitution law, the relator must include factual allegations substantiating that it would have cost less for a SilverScript enrollee to forgo Part D coverage and serially pay cash for generic equivalents. "Describing a mere opportunity for fraud will not suffice." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 158 (3d Cir. 2014). The relator "must provide 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* at 156-157.

The relator's inability to plead any probative cost comparison negates its theory that there was a wide-ranging scheme to violate generic-substitution laws. Its theory is not "complicated and fact-dependent." Opp. 27. It is just wrong. The Court should not allow this fishing expedition. *United States ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185, 195 (4th Cir. 2022).[3]

2. Any noncompliance with state generic-substitution laws is immaterial. Dismissal is further warranted because the relator failed to allege that any violation of a state generic-substitution law was material to the government's decision to pay for coverage. Though the relator extensively describes what it takes to allege materiality (Opp. 27-28), it then unsurprisingly fails to identify anywhere in the SAC where it alleged these necessary facts.

[3] The Court should dismiss the generic-substitution theory in full. At minimum, it must cabin the case only to enrollees actually alleged in the SAC to avoid turning this into an impermissible "fraud action[] where everything is learned after discovery." *Nicholson*, 42 F.4th at 195.

The relator's *only* materiality argument references 42 C.F.R. § 423.104, which requires dispensing drugs on a "valid prescription." Opp. 28. That regulation does not require compliance with a state generic-substitution law. But even assuming it did, the existence of a regulation, even one "expressly identif[ied] as a condition of payment," does not suffice to allege materiality. *Escobar*, 579 U.S. at 194-195 & n.6. Instead, to allege materiality, the relator must include "factual allegations showing that CMS would not have reimbursed these claims had these [alleged false certifications of compliance with state mandatory generic-substitution laws]" not been submitted to the government. *Petratos*, 855 F.3d at 490. The relator has nothing else to offer aside from its tortured construction of "valid prescription." This dooms its claims.

It is no answer to assert that "no one factor [is] necessarily dispositive." Opp. 28-29. Even when viewing the totality of the circumstances, the relator's materiality argument is not plausible. The generic-substitution scheme supposedly "went to the heart of the bargain" because it affected the amount the government reimbursed. Opp. 28-29. But the alternative is that the SilverScript plan would have paid *nothing* for the off-formulary drug, and the enrollee would have had to pay for the prescription herself, which would defeat the purpose of Part D. As the Third Circuit has explained,

> CMS [is] concerned with making sure that the medications [are] dispensed to Medicare recipients and that pharmacies [are] paid for those prescriptions. Had the payments stopped, the prescriptions would not have been dispensed, and the pharmaceutical needs of Medicare recipients would not have been addressed. The misstatements that gave rise to this qui tam action allowed patients to get their medication, and they are precisely the type of 'minor or insubstantial' misstatements where '[m]ateriality ... cannot be found.'"

United States ex rel. Spay v. CVS Caremark Corp., 875 F.3d 746, 764 (3d Cir. 2017). That applies perforce here. It is not plausible that CMS would have preferred that the plan not pay for the on-formulary drug and force Part D enrollees to bear the full cost of a generic equivalent.

The relator has nothing other than an ambiguous regulation to support materiality. That is not enough, particularly when the government has known about these issues for years and has

taken no action to stop Part D plans from employing a brand-preference strategy for certain drugs where it will yield the lowest net cost. *Petratos*, 855 F.3d at 490. This theory must be dismissed.

3. No defendant "knowingly" submitted false claims. Finally, dismissal is further appropriate because the relator failed to allege that defendants "knowingly" submitted a false claim because it is objectively reasonable to interpret the federal regulation and state generic-substitution laws to allow enrollees to use their Part D coverage rather than paying the full cash price for a generic. The opposition hinges on the rejection of *Safeco* (Opp. 29), which applies here.

a. As we explained (at 20), where an interpretation of a legal obligation is not "objectively unreasonable," and there is an absence of guidance "warn[ing] away from [such] an interpretation," a defendant cannot "knowingly" violate the FCA. *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2016). The relator argues this is not the rule in the FCA context. But that is wrong. The Third Circuit, although in an unpublished opinion, has applied *Safeco* to the FCA as have the six other circuits to address whether *Safeco* applies to the FCA.[4]

Even setting aside the overwhelming number of cases applying *Safeco* to FCA claims, such an application would clearly be appropriate. It is impossible for a defendant to "*know* that its claim is false if the requirements for that claim are unknown," even if the defendant "suspect[s], believe[s], or intend[s] to file a false claim." *Schutte*, 9 F.4th at 468. Indeed, the government *itself* has advocated for *Safeco*'s application to FCA claims, observing that the FCA "protect[s] claimants who … rely in good faith on an objectively reasonable interpretation of a contractual or legal duty." U.S. Amicus Br., *Escobar*, 2016 WL 836759, at *10 (Mar. 3, 2016).

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[4] *United States ex rel. Olhausen v. Arriva Med. LLC*, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022) (per curiam); *United States ex rel. Sheldon v. Allergan Sales, LLC*, 2022 WL 4396367, at *1 (4th Cir. Sept. 23, 2022) (en banc) (affirming 499 F. Supp. 3d 184, 207 (D. Md. 2020), without opinion); *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 459 (7th Cir. 2021), *rehearing den.* (Dec. 3, 2021), *pet. for cert. docketed*, No. 21-1326 (U.S. Apr. 5, 2022); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of K.C.*, 833 F.3d 874, 879-880 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290-291 (D.C. Cir. 2015).

The relator strangely ignores the Third Circuit's decision in *Streck*, perhaps because it is unpublished. But it is surely persuasive, given that every other circuit to address the issue agrees with it. What is more, *Streck* relied on the Supreme Court's decision in *Safeco*, a binding Third Circuit decision in *Long v. Tommy Hilfiger U.S.A., Inc.*, 671 F.3d 371, 374-375 (3d Cir. 2012) (applying *Safeco* to a FACTA claim), and the D.C. Circuit's precedential opinion in *Purcell*, 807 F.3d at 287-288. The relator has not provided any reasoned basis for ignoring this overwhelming weight of authority.

Instead, the relator argues that a Third Circuit decision from 1985 in a cocaine-distribution case "foreclose[es] the application of *Safeco*." Opp. 30 (citing *United States v. Caminos*, 770 F.2d 361, 366 (3d Cir. 1985)). That should not be taken seriously. It defies logic to suggest that a Third Circuit decision addressing a drug statute could foreclose the application of a Supreme Court decision that it pre-dates by more than 20 years. The Court should follow *Streck*.

The relator's final argument is that *Safeco* does not apply to FCA claims because the Supreme Court held in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93 (2016), that *Safeco* does not apply to enhanced damages under the Patent Act. Opp. 29. But *Halo* "did not walk back *Safeco* or adopt a new standard for objective recklessness." *Schutte*, 9 F.4th at 467. Instead, it addressed 35 U.S.C. § 284, which allows trebling damages *without* any scienter requirement. *Halo*, 579 U.S. at 96. The FCA, by contrast, limits liability only to *knowing* false claims.

b. Because *Safeco* applies, the relator must explain how the SAC overcomes defendants' objectively reasonable interpretation of the law. The relator comes nowhere close (Opp. 30-31). Indeed, the relator concedes that the Medicare Act allows a plan sponsor to use a brand-preference strategy. It is certainly reasonable for defendants to have followed their interpretation of federal and state law over the relator's absurd one.

The relator thus grasps at straws, arguing that "state of mind" is not amenable to resolution at the pleading stage. Opp. 30-31. That is wrong too. The Court can assess at the pleading stage

whether there exists an objectively reasonable interpretation of the law, an inquiry to which subjective state of mind is irrelevant. *But see* Opp. 30 (citing cases involving subjective intent). The relator also argues that whether CVS was "warned away from their interpretation" is a fact question. Opp. 30. But that puts the cart before the horse. The relator must identify *something* that would warn defendants away from carrying out a CMS-approved formulary notwithstanding a state generic-substitution law.[5] The relator here has *nothing*, and its theory must be dismissed.

B. Imprecise DAW codes do not create a false claim.

As we explained (at 32-38), the relator also fails to state an FCA claim based on submission of prescription drug event (PDE) data with allegedly incorrect Dispense as Written (DAW) codes.

To start, the relator cannot establish falsity by use of DAW Code 9, full stop. Under the old NCPDP standards that CMS uses, DAW Code 9 means "other" and, under the updated NCPDP standards, it means "plan requested brand." The relator persists in arguing that DAW 9 *cannot* be used in a mandatory generic-substitution state because the generic must be substituted. But that restates the relator's generic-substitution theory, not any DAW issue, defeating this theory.

Regardless, none of that matters because the relator fails to allege that *any* DAW coding errors were material in the context of this case nor that they were knowingly used to defraud the government. Thus, the Court should dismiss for those reasons alone.

1. Assuming the Court were to agree that the relator particularly alleged any incorrect DAW codes (which it did not), the fact remains that the relator has not and cannot allege facts to show that noncompliance with DAW coding was material to the government's payment decision in the context of this case. The brands were covered, the generic equivalents were not, and any DAW coding error is immaterial to whether CMS would share in the cost of the claim.

The relator's opposition again depends on its basic misunderstanding of formulary

[5] By contrast, the relator in *United States ex rel. Streck v. Bristol-Myers Squibb Co.* identified CMS statements and a judicial decision. 370 F. Supp. 3d 491, 497-498 (E.D. Pa. 2019).

exceptions. It argues, incorrectly, that defendants "were required to cover non-formulary drugs through Tier 4 cost-sharing." Opp. 32. Again, that is *wrong*. SilverScript is never obligated to grant formulary exceptions to cover non-formulary drugs based on cost. *Supra* at 2-3.

The relator also tries to distinguish "[w]hether the plan would have reimbursed for a prescription from … whether the Government would reimburse for a prescription" because "CMS needs to know not only *what* it is reimbursing, but *why* it is making that payment." Opp. 32-33. That is nonsensical. CMS pays plan sponsors to provide and administer coverage in accord with the CMS-approved formulary. In the scenario here, the brand drug is covered, and it is the only drug covered. The DAW code in that scenario, whether correct or not, is immaterial to the plan's coverage determination and CMS's reason for paying for that coverage.

That much is clear from the CMS guidance the relator cites. It identifies as a "potential fraud, waste and abuse" the "[i]nappropriate use of dispense as written ('DAW') codes." But whatever waste might come from inappropriate use of DAW codes in other scenarios, the relator cannot get around the undeniable failure to plead how DAW codes had *any* impact here. That is the upshot of the Third Circuit's decision in *Spay*, 875 F.3d at 764-765. There, the Court held that "dummy Prescriber IDs" were "precisely the type of 'minor or insubstantial' misstatements where 'materiality … cannot be found'" because they were simply "a technical, formulaic way of preventing a computer program from denying legitimate claims for reimbursement and payment for prescriptions that were actually disbursed to Medicare recipients." *Id.* That reasoning resolves this case too. The bottom line in *this* case is that the DAW codes were immaterial because the brand and only the brand was on-formulary and, thus, the only drug that could be legitimately reimbursed.

Strangely, the relator invokes *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 38 F. Supp. 3d 398, 412 (S.D.N.Y. 2014), where the court *dismissed* concerns about generic substitution and DAW codes that "echo" the relator's here. Opp. 33. This case should meet the same end.

Ultimately, the relator has failed to plead any facts showing that any material misrepresentation occurred. Indeed, CMS has known about these types of allegations for years from *FoxRx* and this case and has taken no action to change its DAW coding instructions. At bottom, the plan would cover the brand drug no matter what, precluding a materiality finding.

2. The relator has also failed to allege that any defendant acted to "knowingly" defraud the government by using incorrect DAW codes. Nonetheless, the relator contends that it has alleged sufficient facts to show "knowing" DAW code misuse by repeating all of its high-level complaints about defendants' brand-preference strategy. Opp. 34.

But none of these allegations gets the relator to a knowing falsification of DAW codes as some fraudulent "cover-up." The relator cannot even articulate a plausible and coherent "scheme" for the DAW codes (other than to argue that every single one was necessarily wrong). What is more, CVS Pharmacy is not the only pharmacy to fill prescriptions for SilverScript enrollees. The SAC attaches records regarding *non*-CVS-affiliated pharmacies filling brand prescriptions that include an array of DAW codes,[6] and the relator has failed to plausibly allege that any pharmacists at those pharmacies knowingly falsified DAW codes (which again underscores the immateriality).

And even if the relator had alleged knowledge at all (and it has not), under *Safeco*, it is an objectively reasonable interpretation of the law that a pharmacy can dispense a covered brand drug consistent with an enrollee's insurance coverage regardless of whether a DAW code fully fits the circumstances. The relator's interpretation would require the pharmacist to either force the enrollee

[6] Ex. 22 (redacted pharmacy filing Invega with DAW 9); Ex. 38 (redacted pharmacy filling Epclusa with DAW 0); Ex. 43 (redacted pharmacy filling Epclusa with DAW 0); Ex. 46 (redacted pharmacy filling Epclusa with DAW 1); Ex. 50 (redacted pharmacy filling Epclusa with DAW 0); Ex. 53 (redacted pharmacy filling Epclusa with DAW 0); Ex. 54 (redacted pharmacy filling Epclusa with DAW 0); Ex. 59 (redacted pharmacy filling Harvoni with DAW 0); Ex. 64 (Kroger pharmacy filling Ventolin HFA with DAW 2). The only reasonable inference is that the fully redacted pharmacies are non-CVS-affiliated given that the relator has elsewhere left CVS-affiliated pharmacies unredacted. Defendants have been hindered from validating the identity of these pharmacies by the relator's refusal to produce an unredacted version of the SAC. Dkt. 40.

to forego her insurance coverage or submit a false claim, which is plainly unreasonable.

In sum, the relator's theory based on allegedly inaccurate DAW codes must be dismissed.

C. Denying formulary exception requests is not a false claim.

As explained in the opening brief (at 38-40) and further above (*supra* at 2-3), a plan sponsor need only grant a formulary exception if two criteria are met. First, the plan sponsor must find that the drug is "medically necessary" for the individual enrollee, consistent with a prescriber's statement that all Part D drugs on any tier of the formulary would not be "as effective" or would produce "adverse effects" for the individual enrollee as a *clinical* matter. 42 C.F.R. § 423.578(b)(5). Second, the plan sponsor must make the non-clinical finding that "the drug would be covered but for the fact that it is an off-formulary drug." *Id.* § 423.578(b). The relator's response is to belabor over *six* pages its theory that enrollees paid more and were deceived by the brand-preference strategy. Opp. 35-41. But that is irrelevant. The premise that formulary exceptions must be granted based on cost is patently wrong and, without it, the relator's argument is just noise.

A "medical necessity" determination—a prescriber's assessment of adverse effects or comparative effectiveness of on-formulary drugs versus the off-formulary drug—is *clinical*. Indeed, the regulation itself directs the prescriber to look at *all* on-formulary drugs, without regard to the cost-sharing under each tier. And the Medicare Appeals Council—the final agency decisionmaker on exception-request denials (42 C.F.R. § 423.2100, 2130)—has held that "[t]he formulary exception process [] may not be used solely on the basis that a drug is cost prohibitive to an enrollee." *Case of A.S.*, 2013 WL 7872029, at *3.

The relator's interpretation that formulary exceptions must be granted based on cost should be rejected because it is counter-textual, finds no support in agency guidance, and would upend a plan's carefully curated choices about plan economics. At a bare minimum, defendants' interpretation of the regulation as requiring formulary exceptions only for clinical reasons is reasonable, and the relator thus cannot allege that any supposed violation was done "knowingly."

At bottom, there is nothing false or fraudulent about denying a formulary exception request based on "cost" concerns. Indeed, CMS authorized plan sponsors to do just that and established a multi-step process whereby enrollees may seek administrative and judicial review of such denials. *See* 42 C.F.R. § 423.578(c)(1), 423.558 *et seq.*, 423.1968 *et seq.*; *Medicare Prescription Drug Coverage Appeals*, Medicare.gov (as of Oct. 22, 2022), perma.cc/PT75-22HR. If CMS wanted to turn its appeal process inside out and mandate exceptions for cost, then it would have done so expressly and not through the narrow clinical exception argued by the relator.

The relator tries to save face by arguing that defendants discouraged enrollees from filing administrative appeals. Opp. 40. But even if that were true (and it is not), communications to enrollees about the exceptions review process cannot work a fraud *on the government* and are thus not actionable under the FCA. The Court must dismiss the SAC for that reason as well.

D. Marketing materials did not give rise to false claims.

As explained in our opening brief (at 40-44), the relator also failed to allege fraud on the government based on alleged deception of plan members through marketing materials and call center statements. Indeed, relator concedes as much when it acknowledges in opposition that its allegation is that Part D *enrollees* were "fraudulently induced" to *join* SilverScript's plan. Opp. 41. But allegedly deceiving enrollees into joining a plan is *not* deceiving the government into paying claims it should not have, and there is no allegation that the *government* would have refused to pay its share for covering an undisputedly covered brand drug based on marketing. These statements cannot give rise to false claims for payment submitted to the government and must be dismissed.

1. To start, the relator fails to allege a required causal link between the alleged false marketing statements and the submission of a false claim to the government. The Third Circuit requires that the alleged falsehood was "*integral* to a causal chain leading to payment." *Petratos*, 855 F.3d at 491 (citation omitted). The relator's alleged "causal chain" is instead long and tenuous. The relator alleges that SilverScript made marketing misrepresentations to potential customers;

customers decided to join SilverScript's Part D plan based on those misrepresentations; then, eventually, the now-SilverScript enrollees submitted claims to the government for the brand drug. Opp. 41. But SilverScript enrollees do not submit claims to the government and, in any event, the relator does not establish a misrepresentation proximately causing payment of a claim.

Fundamentally, the relator has not alleged that any marketing or call center statements defendants made were integral to the *government's* decision to pay SilverScript. Absent from the 678-page SAC is any allegation that the government would have rejected any claims had it known about defendants' marketing or call center statements that the relator criticizes. There is no link between the alleged marketing tactics and government payment, destroying this theory.

Indeed, the allegedly fraudulent call center statements do not even fit into relator's flimsy "causal chain." They were made to *existing* SilverScript enrollees. Thus, they could not possibly be a "substantial factor in causing SilverScript beneficiaries to choose its plans." Opp. 43.

2. The marketing materials and call center statements were also not false, nor could they have produced a false claim. As an initial matter, when submitting a claim for a covered drug, no defendant expressly or impliedly certified compliance with plan-marketing regulations. *Escobar*, 579 U.S. at 190 (for implied certification, "the claim [must] make[] specific representations about the goods or services provided" that would be "misleading half-truths" if a particular regulation were unsatisfied). Regardless, the relator fails to allege how any communications did not comply with CMS regulations. Vaguely asserting that certain statements were not "clear" or "accurate" (Opp. 44) and taking particular umbrage at marketing materials that focused on the enrollee (*e.g.*, Opp. 41-42) does not establish regulatory noncompliance.

The relator nonetheless persists in contending that these statements were "materially inaccurate" because they should have said, for example, that SilverScript "helps you save money only some of the time." SAC ¶ 243. But SilverScript's marketing language is true. The relator cannot allege that enrollees would pay less for their drugs if they declined to participate in

SilverScript's Part D plan; instead, the relator merely alleges that enrollees could have saved *more* money on their drugs had SilverScript made different choices about its formulary. Maybe so. But that does not make it misleading to say that enrollees save money by joining its plan.

And, regardless, these types of general statements are considered "puffery." Vague expressions of hope or optimism are simply not actionable. *Brucker v. State Farm Mut. Auto. Ins. Co.*, 2017 WL 7732876, at *3-4 (W.D. Pa. May 26, 2017) (slogans like "Nationwide is on your side," "You're in good hands with Allstate," and "like a good neighbor, State Farm is there"); *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 283 (3d Cir. 2010) (dismissing allegations of securities fraud; "a representation is immaterial if the statement at issue is too vague to be actionable"). Absent any specific falsehood, the relator cannot cry "fraud" based on vague marketing statements.

All this aside, the relator's falsity assertions fail for the yet further reason that they hinge on its misunderstanding of formulary exceptions. Opp. 44-47. Again, formulary exceptions *are not available* for cost-based considerations. *Supra* at 2-3. Defendants cannot have misled enrollees as to formulary exceptions or relative costs of covered brand versus *non-covered* generics in the manner the relator contends because formulary exceptions are not available to defray costs.

The call center statements were also not misleading. The relator features its three best examples, but they are *all* truthful. It is *true* that if enrollees got a formulary exception for a generic, it would be on the "highest cost share level" under the enrollee's plan. Opp. 46. It is *true* that "generic drugs were not available on the formulary because of 'market conditions outside [defendants'] control'" (Opp. 47)—for example, because the generic drug pricing (which is out of defendants' control) had not reached a suitable level. *See* SAC ¶ 385. And it is *true* that enrollees could request formulary exceptions for Harvoni and Epclusa. Opp. 47. Even taking as true the relator's thinly pled allegation of some agreement to wholesale deny formulary exceptions, the relator does not plausibly allege that SilverScript *could have* blocked enrollees from applying for formulary exceptions because, of course, had the enrollees requested and been denied formulary

exceptions, they could have pursued multiple levels of independent administrative and judicial review, eliminating any taint from this utterly implausible agreement.

3. The SilverScript marketing statements also could not possibly be material to CMS's decision to pay for on-formulary brand drugs. Materiality requires the relator to allege that the government "consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 195. Here, CMS pays a portion of the cost of enrollees' drugs that are on SilverScript's formulary and that cost is unaffected by any statements SilverScript allegedly made to enrollees regarding the reasons those drugs are on the formulary and certain generic drugs are not.

4. Finally, the relator fails to allege that anyone "knowingly" violated any obligation to disclose cost differentials. For the reasons discussed, the relator cannot rely on the allegation that defendants "deceived beneficiaries into believing generic drugs covered under a formulary exception would be more expensive than on-formulary brand-name drugs" (Opp. 48)—because the statute and regulations did not require SilverScript to grant a formulary exception based on cost and apply Tier 4 cost-sharing. The relator's argument that defendants made public statements and covertly monitored customer satisfaction to "cover up" an alleged scheme has no bearing on whether defendants' reading of the statutes and regulations was objectively reasonable.

E. CVS Health's compliance program did not give rise to a false claim.

As the opening brief explained (at 44), the relator's false certification claim premised on "compliance program" issues fails because defendants *did* have a compliance program and because the underlying allegations of defendants' unlawful conduct are meritless. Nonetheless, the relator gripes about legal noncompliance under its *other* theories. Opp. 50. This, of course, is strong proof that a deficiency in defendants' compliance program is not an independent basis for FCA liability.

The relator nonetheless asserts that "defendants" collectively "falsely certified that their compliance program was adequate to ensure the integrity of its claims" when instead it was

"insufficient" and a "sham." Opp. 49-50. But that does not state an FCA claim either.

First, the relator has not alleged a single violation that the compliance program missed.

Second, the relator fails to allege how defendants' compliance program failed to comply with federal law, including the requirements at 42 C.F.R. § 423.504(b)(4)(vi). Instead, the relator simply labels the compliance program a "sham" because defendants monitored for member complaints about the brand-preference strategy. Opp. 50. But the relator fails to connect this alleged monitoring initiative to noncompliance with anything in Section 423.504(b)(4)(vi).

Third, setting all that aside, the relator fails to explain how any deficiency in the compliance program on its own created a false claim. The relator does not identify any express certification by defendants *about their compliance program* when submitting a claim. Thus, the relator must mean that, when submitting each claim, defendants impliedly falsely certified that their compliance program was sufficient to catch all the other (meritless) frauds the relator alleges. That is several bridges too far. *Escobar*, 579 U.S. at 190 (requiring allegations that the government would consistently refuse to pay claims based on noncompliance with the particular regulation).

The relator's claims premised on compliance program deficiencies should be dismissed.

F. Alleged violations of a firewall or FTC consent order are not false claims.

As we explained (at 44-46), the relator's allegations about violations of an alleged firewall agreement and an FTC consent order have nothing to do with supposed fraud on Part D and, as such, do not give rise to FCA liability. The opposition provides only two incorrect legal arguments.

First, the relator admits that the 2007 firewall and FTC consent order are not laws. Thus, a certification about compliance with laws cannot have embraced those. Nonetheless, the relator argues that, because the firewall and consent order were *premised* on laws administered by the FTC that prevent fraud *on consumers*, that means the firewall and consent order are laws preventing fraud on the government. Opp. 52. The relator has no support for the notion that, by certifying compliance with laws specifically designed to prevent fraud on the government, a

company certifies compliance with non-laws and consumer-protection statutes. And, indeed, it admits it has not alleged that compliance with non-laws and consumer-protection statutes is material to CMS's payment decision. Opp. 53. Repackaging the theory as a "reverse false claim" cannot save the relator's claims as to the Part D program. *United States ex rel. Alejandro v. Phila. Vision Ctr.*, 2022 WL 294548, at *9 (E.D. Pa. Feb. 1, 2022) (dismissing redundant reverse false claims). As to the Part D program, the relator's theory is redundant and must be dismissed.

Second, without fraud on CMS, the relator shifts course entirely, alleging that the reverse false claim flows from the failure to voluntarily pay penalties to the FTC. Opp. 53. Not so.

The FCA's reverse claims provision requires a "clear obligation or liability to the government." *United States ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 514 (E.D. Pa. 2010) (quotation marks omitted). This duty must be "owed at the time that the alleged improper conduct under the FCA occurred" but "does *not* include a duty that is dependent on a future discretionary act." *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 505 (3d Cir. 2017); *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 446 (3d Cir. 2004) (without a clear obligation to credit the government, no FCA liability could be imposed). Regulatory fines and penalties are not considered "obligations" because they are contingent on the government's prosecutorial discretion. *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 279 (E.D. Pa. 2020).

Worse, the only "obligation" the relator identifies is an extra-contractual statement in a letter stating that CVS Health might "be liable for civil monetary penalties of up to $16,000 per violation" of the consent order. SAC ¶ 262. In the relator's telling, because defendants have not voluntarily paid penalties under the FTC Act to the FTC, that is a reverse false claim. Absurd. Although an "obligation" to pay the government can arise from a "contractual obligation," like a stipulated penalty provision (*United States ex rel. Boise v. Cephalon, Inc.*, 2015 WL 4461793, at *4 (E.D. Pa. July 21, 2015)), the relator does not allege *any* such contractual obligation on defendants' part. Having realized the firewall and consent order are irrelevant, the relator tries to

manufacture an obligation to pay the FTC. But it fails to state a claim there either.

III. THE RELATOR FAILS TO SALVAGE ITS CONSPIRACY CLAIM.

Defendants' opening brief explained (at 46-48) that the relator's conspiracy claim fails not only because it has not alleged any FCA violation but also because it has not plausibly alleged an agreement between Caremark and drug manufacturers to violate the FCA. In response, the relator tries to redefine an FCA conspiracy and to rewrite the SAC. But this effort fails.

To start, the relator suggests that it need only "general[ly] describe the conspiracy and its participants." Opp. 55. Not so. To allege an FCA conspiracy, the relator must plausibly allege "an explicit agreement between the entities to conspire to violate the FCA, which is the essential element of a FCA conspiracy claim." *United States v. Medco Health Sys., Inc.*, 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014); *United States ex rel. Atkinson v. Pa. Shipbuilding Co*., 2000 WL 1207162, at *11 (E.D. Pa. Aug. 24, 2000) (collecting cases; "without allegations of an agreement to defraud, the claim must be dismissed"). Though initially resistant, the relator eventually accedes, acknowledging that Section 3729(a)(1)(C) requires agreeing "to commit a fraud." Opp. 55.

The relator fails in trying to explain how it plausibly alleged an agreement to defraud the government, as opposed to an ordinary rebate agreement. The relator simply regurgitates its allegations about the harms to enrollees from rebate agreements and then concludes that "it was foreseeable that Defendants' conduct to block access to generic drugs would result in false claims being submitted to the Government." Opp. 55-56. But a "foreseeable" consequence and an agreement to cause a consequence are two entirely different concepts; a "foreseeable consequence does not subsume the aim of the agreement." *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 917 (6th Cir. 2017). It is "not enough … to show there was an agreement that made it *likely* there would be a violation of the FCA; [the relator] must show an agreement was made *in order to* violate the FCA." *Id.*

The relator has not done so. *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D.

113, 123-124 (W.D. Pa. 2006) (dismissing FCA conspiracy where "[t]he only allegation of an agreement to defraud the Government … is conclusory in nature"). And the cases it relies on only confirm that conclusion. In *Travis*, the Court rejected most of the conspiracy theories but allowed conspiracy claims to survive with respect to bribes and kickbacks. But a plausible agreement to pay or accept a bribe or kickback suggests an agreement to violate the FCA because paying or accepting a bribe or kickback in violation of the anti-kickback statute *is also* an FCA violation. *Travis*, 2022 WL 991382, at *10-11; *United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 523 (E.D. Pa. 2015) (kickbacks). The relator has not alleged bribes or kickbacks nor any other basis for an intentionally fraudulent rebate agreement. It instead only complains about "foreseeable consequences" that resulted. But that does not transform a rebate agreement into a plausible agreement intended to defraud the government.

IV. THIS ACTION IS BARRED BY THE PUBLIC-DISCLOSURE BAR.

This action must also be dismissed because the fraud was publicly disclosed. MTD 48-54.

A. Public documents—CMS communications, newspaper articles, and a Senate hearing—"set out the allegation of fraud itself [Z] or its essential elements [X+Y]" and bar relator's action. *United States ex rel. Silver v. Omnicare, Inc.*, 903 F.3d 78, 84 (3d Cir. 2018). Indeed, the relator *admits* this, acknowledging defendants' alleged brand-preference scheme, violations of state generic-substitution laws, and submissions of incorrect DAW codes were set out in public disclosures. Opp. 58. That admission should end matters (at minimum, as to these theories).

Nonetheless, to avoid the public disclosure bar, the relator reframes secondary theories of alleged wrongdoing as the heart of the supposed fraudulent scheme. The alleged brand-preference scheme, violations of generic-substitution laws, and incorrect DAW codes are now just "context" for the real fraudulent scheme: a hodgepodge of supposed unlawful activities, none of which violate the FCA—rebate agreements that allegedly violate antitrust laws, not stocking off-formulary generics, misleading about costs of brand-name versus generic drugs, discouraging

formulary exceptions, and violating obligations to the FTC. Opp. 58-59. Because none of those activities even arguably violate the FCA, none bear on the public disclosure bar analysis.

What is more, the relator's newfound emphasis on alleged antitrust violations is especially strange because the April 2019 Senate Finance Committee hearing focused expressly on allegedly anti-competitive rebate agreements. *Drug Pricing in America: A Prescription for Change, Part III: Hearings before the S. Committee on Finance*, 116th Cong. 415 at 2, 34, 226 (2019) ("investigating pricing and rebating practices"; expressing "concern" about "rebate walls" that incentivize exclusion of competitors from formularies). Indeed, CVS Health denied that it agreed to "rebate walls" and produced its rebate agreements, which the Committee published online. *Documents Produced by CVS Health Corp. (CVS Caremark)*, perma.cc/5863-4TJW. Thus, even if antitrust violations were somehow actionable under the FCA (they are not), the public disclosure bar still applies because the relator's allegations about anticompetitive rebate agreements were publicly disclosed in the hearing, along with the actual terms of the rebate agreements.

B. The relator argues that even if the public disclosure bar applies, the action need not be dismissed because the relator is an "original source." Opp. 60-64. But the relator is wrong. As CVS explained in its opening brief (MTD 52-53), Congress unambiguously limited "original source" status only to "individual[s]" (31 U.S.C. § 3730(e)(4)(B)), *not* to corporate entities.

The plain and ordinary meaning of an "individual" is a natural person (*Clinton v. City of New York*, 524 U.S. 417, 428 n.13 (1998)), a conclusion compelled by 1 U.S.C. § 1, which applies "[i]n determining the meaning of any Act of Congress, unless the context indicates otherwise."

The relator resists this conclusion, but none of the cases it cites support departing from the text. To start, *Clinton v. City of New York* supports our reading. There, the Supreme Court agreed that "in ordinary usage both 'individual' and 'person' often refer to an individual human being, [although] 'person' often has a broader meaning in the law." 524 U.S. at 428 n.13, 429. That proves our point—the plain and ordinary meaning of "individual" is a human being and is distinct from a

"person." Although *Clinton* construed the term "individual" within the Line Item Veto Act to be "synonymous" with the term "person," it did so based on the Act's unique structure and purpose and its view that "Congress did not intend the result that the word 'individual' would dictate in other contexts." *Id.* at 428-429. But the FCA's public-disclosure bar has a different purpose—"to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" (*Graham Cnty. Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294-295 (2010))—and the relator has not made any argument as to why Congress would have deviated from the ordinary meaning of "individual" in *this* context. It makes sense that Congress would limit original sources to individuals to encourage whistleblowing by corporate insiders who witness fraudulent activity, as opposed to corporate entities formed for litigation purposes, like the relator. The far better view is that Congress intentionally used different language to allow only "individuals" to qualify as original sources, even if "persons" may bring FCA claims.

The relator is wrong to suggest that *United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 304-308 (3d Cir. 2016), held otherwise. Neither party argued that the term "individual" in the FCA is limited to human beings, so the court did not consider it. And the unreasoned conclusion by the Eighth Circuit in a footnote is not persuasive (*Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1048 nn.12-13 (8th Cir. 2002)) in the face of the FCA's plain text, 1 U.S.C. § 1, and the purpose of the public-disclosure bar.

Even if a corporate entity could qualify as an original source, the relator has not alleged that it has knowledge that materially adds anything. 31 U.S.C. § 3730(e)(4)(B). The SAC contains only conclusory statements about the knowledge of one of relator's partners, Ms. Miller. Opp. 63; SAC ¶¶ 33-36, 116-118. Because nothing in the SAC "adds in a significant way to the essential factual background" (*Moore*, 812 F.3d at 307), the relator cannot be an "original source."

CONCLUSION

The Court should grant the motion to dismiss.

Dated: October 24, 2022

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CERTIFICATE OF SERVICE

I certify that on October 24, 2022, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/ *Lesli C. Esposito*